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| 09/741,542 | 12/20/2000 | Christof Fattinger | 9492 | 6425 |
| 151 | 7590 12/26/2002 | | | |
| HOFFMANN-LA ROCHE INC. | | | EXAMINER | |
| | W DEPARTMENT AND STREET | | QUAN, ELIZ | ZABETH S |
| NUTLEY, N | J 07110 | | ART UNIT | PAPER NUMBER |
| | | | 1743 | <u> </u> |
| | | | DATE MAILED: 12/26/2002 | 9 |

Please find below and/or attached an Office communication concerning this application or proceeding.

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|---|---|------------------------------------|---|--|--|
| | | Application No. | Applicant(s) | | |
| Office Anti-en Order | | 09/741,542 | FATTINGER ET AL. | | |
| | Office Action Summary | Examiner | Art Unit | | |
| | | Elizabeth Quan | 1743 | | |
| Period fo | The MAILING DATE of this communication app or Reply | ears on the cover sheet with the c | orrespondence address | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status | | | | | |
| 1) | Responsive to communication(s) filed on | | | | |
| 2a)⊠ | · · · · <u> </u> | s action is non-final. | | | |
| 3) | | | | | |
| Disposition of Claims | | | | | |
| 4) Claim(s) 1-5 is/are pending in the application. | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| 5)□ | Claim(s) is/are allowed. | | | | |
| 6)⊠ | Claim(s) <u>1-5</u> is/are rejected. | | | | |
| 7) | Claim(s) is/are objected to. | | | | |
| · · | Claim(s) are subject to restriction and/or | election requirement. | | | |
| Application Papers | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | |
| Priority u | ınder 35 U.S.C. §§ 119 and 120 | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | |
| a)□ All b)□ Some * c)□ None of: | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | |
| a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | |
| Attachment(s) | | | | | |
| 2) Notice | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s) | 5) Notice of Informal I | y (PTO-413) Paper No(s) Patent Application (PTO-152) | | |
| S. Patent and Tr | ndamad Office | | | | |

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DETAILED ACTION

Drawings

1. This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 2. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 5,080,232 to Leoncavallo.

Referring to claims 1 and 4, Leoncavallo discloses a rack (10, 20) for use in a compound handling system for handling a multiplicity of tubes containing aliquots of chemical or biological samples. The rack comprises a single piece frame (22) with a top side and bottom side and storage compartments (24) configured and dimensioned to receive a sample tube containing chemical or biological sample (see FIGS. 2, 3, and 6; COL. 2, lines 40-66). The storage compartments (24), each of which has an inner wall, are open at the top and bottom side of the frame (22) so that a sample tube can be inserted within the inner wall of the storage compartment and into the storage compartment (24) from either the top or bottom side of the frame (22) with one and the same orientation of the sample tube with respect to the frame (22) (see FIGS. 2, 3, and 6; COL. 2, lines 40-66). The retaining means (34) for retaining a sample tube within each of the storage

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compartments (24) is an integral part of the frame (22) as part of the inner wall of each storage compartment (24) (see FIGS. 2, 3, and 6; COL. 3, lines 32-59). The retaining means (34) is configured and dimensioned to cooperate with a part of the outer wall of a sample tube in order to retain the sample tube at a predetermined position within the compartment (24) (see FIGS. 2, 3, and 6; COL. 3, lines 32-59). The retaining means (34) for retaining a sample tube (36) comprises a projection of the inner wall of each storage compartment (24) that is configured and dimensioned to bias against a sample tube (36) positioned within the storage compartment (24) (see FIGS. 2, 3, and 6; COL. 3, lines 32-59). Therefore, Leoncavallo includes all the limitations in claims 1 and 4.

3. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 5,579,929 to Schwartz.

Referring to claims 1 and 4, Schwartz discloses a rack (1) for use in a compound handling system for handling a multiplicity of tubes containing aliquots of chemical or biological samples. The rack comprises a single piece frame (11) with a top side and bottom side and storage compartments (14) configured and dimensioned to receive a sample tube containing chemical or biological sample (see FIGS. 1 and 1a; COL. 6, lines 46-55). The storage compartments (14), each of which has an inner wall, are open at the top and bottom side of the frame (11) so that a sample tube can be inserted within the inner wall of the storage compartment and into the storage compartment (14) from either the top or bottom side of the frame (11) with one and the same orientation of the sample tube with respect to the frame (11) (see FIGS. 1 and 1a; COL. 6, lines 46-55). The retaining means (24, 25) for retaining a sample tube within each of the storage

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compartments (14) is an integral part of the frame (11) as part of the inner wall of each storage compartment (14) (see FIGS. 1, 1a, and 2; COL. 6, lines 46-55; COL. 7, lines 4-67; COL. 8, lines 1-65). The retaining means (24, 25) is configured and dimensioned to cooperate with a part of the outer wall of a sample tube in order to retain the sample tube at a predetermined position within the compartment (14) (see FIGS. 1, 1a, and 2; COL. 6, lines 46-55; COL. 7, lines 4-67; COL. 8, lines 1-65). The retaining means (24, 25) for retaining a sample tube (10) comprises a projection of the inner wall of each storage compartment (14) that is configured and dimensioned to bias against a sample tube (10) positioned within the storage compartment (14) (see FIGS. 1, 1a, and 2; COL. 6, lines 46-55; COL. 7, lines 4-67; COL. 8, lines 1-65). Therefore, Schwartz includes all the limitations in claims 1 and 4.

Claim Rejections - 35 USC § 103

- 4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 5. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,080,232 to Leoncavallo as applied to claim 1 above, and further in view of U.S. Patent No. 5,048,957 to Berthold et al.

Referring to claim 2, while Leoncavallo does not disclose compartments configured and dimensioned to receive an entire sample tube, Berthold et al. show cuvettes (20) entirely enclosed within the cuboid blocks (10) of the specimen rack (see FIG. 2; COL. 4, lines 21-25). Berthold et al. do not explicitly state why the cuvettes (20) are completely enclosed within the cuboid blocks (10) of the specimen rack; however, it

appears the enclosure protects light-sensitive samples. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the rack of Leoncavallo by extending the inner walls of the storage compartments to completely enclose the sample tubes within the compartments as in Berthold to protect light-sensitive samples.

6. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,579,929 to Schwartz as applied to claim 1 above, and further in view of U.S. Patent No. 5,048,957 to Berthold et al.

Referring to claim 2, while Schwartz does not disclose compartments configured and dimensioned to receive an entire sample tube, Berthold et al. show cuvettes (20) entirely enclosed within the cuboid blocks (10) of the specimen rack (see FIG. 2; COL. 4, lines 21-25). Berthold et al. do not explicitly state why the cuvettes (20) are completely enclosed within the cuboid blocks (10) of the specimen rack; however, it appears the enclosure protects light-sensitive samples. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the rack of Schwartz by extending the inner walls of the storage compartments to completely enclose the sample tubes within the compartments as in Berthold to protect light-sensitive samples.

7. Claims 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,080,232 to Leoncavallo as applied to claim 1 above, and further in view of U.S. Patent No. 5,514,343 to Verwohlt et al.

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Referring to claim 3, Leoncavallo acknowledges that the storage compartments (24) may have any desired shape (see COL. 2, lines 67 and 68; COL. 3, line 1). While Leoncavallo do not explicitly disclose rectangular storage compartments, it is well known in the art to employ rectangular storage compartments as evidenced by Verwohlt et al. Verwohlt et al. disclose that the apertures (13) may have a polygonal shape, such as a rectangle or square (see COL. 2, lines 13-14). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the rack of Leoncavallo to use the convention rectangular storage compartments as in Verwohlt as desired.

Referring to claim 5, Leoncavallo discloses a projection (34) capable of snapping in between two ridges of the outer wall of a sample tube. Leoncavallo does not disclose a sample tube with two ridges on its outer wall. Verwohlt et al. disclose tubes (16) with two ridges forming a groove (22) with which a projection can snap into firm engagement (see FIGS. 3 and 4; COL. 5, lines 6-14). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the rack of Leoncavallo to include a tube with two ridges forming a groove for engagement with a projection as in Verwohlt et al. for firmly grasping and fixing the position of the tube.

8. Claims 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,579,929 to Schwartz as applied to claim 1 above, and further in view of U.S. Patent No. 5,514,343 to Verwohlt et al.

Referring to claim 3, Schwartz does not explicitly disclose rectangular storage compartments, it is well known in the art to employ rectangular storage compartments as

evidenced by Verwohlt et al. Verwohlt et al. disclose that the apertures (13) may have a polygonal shape, such as a rectangle or square (see COL. 2, lines 13-14). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the rack of Schwartz to use the convention rectangular storage compartments as in Verwohlt as desired.

Referring to claim 5, Schwartz discloses a projection (24, 25) capable of snapping in between two ridges of the outer wall of a sample tube. Schwartz does not disclose a sample tube with two ridges on its outer wall. Verwohlt et al. disclose tubes (16) with two ridges forming a groove (22) with which a projection can snap into firm engagement (see FIGS. 3 and 4; COL. 5, lines 6-14). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the rack of Schwartz to include a tube with two ridges forming a groove for engagement with a projection as in Verwohlt et al. for firmly grasping and fixing the position of the tube.

Response to Arguments

- 1. Applicant's arguments filed 10/15/2002 have been fully considered but they are not persuasive.
- 2. Referring to claims 1 and 4, Applicant maintains that neither Leoncavallo nor Schwartz disclose any storage compartments for a sample tube, but only openings or cutouts (24) of a shelf (12) through which a sample tube can be inserted. Applicant further maintains that the retaining means disclosed by Leoncavallo or Schwartz do not retain a sample tube at a predetermined position but at any position within a predetermined range. Applicant further maintains that Leoncavallo or Schwartz only discloses insertion of a sample tube into openings (24) from above

and nowhere does Leoncavallo or Schwartz even hint at inserting a sample tube into openings (24) from below. Applicant further maintains that insertion of the tubes from below is not possible with the shapes of the tubes and the shapes of the retaining means disclosed by Leoncavallo or Schwartz.

According to Merriam-Webster's Collegiate Dictionary, a compartment is 1: a separate division or section or 2: one of the parts into which an enclosed space is divided. The "openings or cutouts" are separate divisions or sections or one of the parts into which an enclosed space is divided. Each compartment or divided section holds a sample tube. Both the drawings and specification describe the storage compartment as openings. Referring to FIGS. 1-3, the storage compartments (5) are openings. The specification states on page 3, lines 25-27: "The storage compartments (5) are open at both ends, i.e. at the top surface and bottom surface of rack (1). The purpose of the two openings will be explained later in this specification." Leoncavallo or Schwartz discloses storage compartments open at both ends at the top and bottom surface of rack (see Leoncavallo: FIGS. 2, 3, and 6; COL. 2, lines 40-66; Schwartz: FIGS. 1 and 1a; COL. 6, lines 46-55).

Any position within a predetermined range is a predetermined position among possible predetermined positions within a predetermined range. Examiner emphasizes that the manner of operating the device does not differentiate the apparatus claims from the prior art. MPEP 2114. A recitation with respect to the manner in which a claimed apparatus is intended to be employed, such as the position the retaining means retains the sample tube, does not differentiate the claimed apparatus from a prior art apparatus if the

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prior art apparatus teaches all of the structural limitations of the claims. Therefore, since Leoncavallo or Schwartz teaches the all the structural limitations of the claims including the retaining means, the claimed apparatus cannot be differentiated from Leoncavallo or Schwartz based on the position the retaining means retains the sample tube.

While Leoncavallo or Schwartz does not explicitly disclose inserting a sample tube into the openings from below, the claim gives the option of "...a sample tube is insertable into the storage compartment from either the top side of the frame or the bottom side of the frame." Therefore, inserting the sample tube from the top as in Leoncavallo or Schwartz meets the limitation. According to Merriam-Webster's Collegiate Dictionary, -able means capable of. The language insertable means capable to insert or to be inserted. Since the compartments are open at both ends, the sample tube is insertable from the top and below. The shape of the storage compartments and retaining means do not prevent the sample tube from being inserted from below. The shapes of the storage compartments and retaining means are the same top and bottom. If it is insertable from the top, it is insertable from the bottom. Examiner emphasizes that the manner of operating the device does not differentiate the apparatus claims from the prior art. MPEP 2114. A recitation with respect to the manner in which a claimed apparatus is intended to be employed, such as inserting sample tubes from the bottom, does not differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches all of the structural limitations of the claims. Therefore, since Leoncavallo or Schwartz teaches all the structural limitations of the claims including the compartment open at the top and

bottom, the claimed apparatus cannot be differentiated from Leoncavallo or Schwartz based on inserting sample tubes from the bottom.

Referring to claim 4, Examiner notes that the retaining means of the primary references are capable of interacting with any feature—wall, ridge, etc.—to retain the tube in a desired position.

3. Referring to claim 2, Applicant maintains that neither Leoncavallo nor Schwartz disclose any storage compartment for a sample tube, but only openings or cutouts (24) of a shelf (12) through which a sample tube can be inserted, and therefore, Leoncavallo or Schwartz cannot suggest storage compartments each of which is adapted for holding an entire sample tube. Applicant further maintains Berthold discloses storage compartments each of which is adapted to receive an entire sample tube, but the storage compartments disclosed by Berthold have no retaining means of the kind mandated by the Applicant's claim. Applicant further maintains that Berthold fails to disclose storage compartments that allow insertion of sample tubes from below. Applicant further maintains that no combination of Leoncavallo or Schwartz and Berthold suggest the claimed invention.

As previously discussed, Leoncavallo or Schwartz discloses storage compartment with open at the top and bottom as required by the claim and defined by the specification. Applicant admits that Berthold discloses storage compartments adapted to receive an entire sample tube, meeting the limitation in claim 2. It does not matter if the secondary reference Berthold does not disclose retaining means or storage compartments allowing insertion of sample tubes from below, as the reference serve to provide the limitation of the storage compartments adapted to receive an entire sample tube not explicitly

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disclosed by the primary reference and the motivation for providing the limitation.

Leoncavallo or Schwartz already provides the limitation of retaining means and the capability of inserting the tube from the bottom is inherent to the apparatus of Leoncavallo or Schwartz.

While Leoncavallo, Schwartz, or Berthold does not explicitly disclose inserting a sample tube into the openings from below, the claim gives the option of "...a sample tube is insertable into the storage compartment from either the top side of the frame or the bottom side of the frame." Therefore, inserting the sample tube from the top as in Leoncavallo, Schwartz, or Berthold meets the limitation. According to Merriam-Webster's Collegiate Dictionary, -able means capable of. The language insertable means capable to insert or to be inserted. Since the compartments of Leoncavallo or Schwartz are open at both ends, the sample tube is insertable from the top and below. The shape of the storage compartments and retaining means do not prevent the sample tube from being inserted from below. The shapes of the storage compartments and retaining means are the same top and bottom. If it is insertable from the top, it is insertable from the bottom. Examiner emphasizes that the manner of operating the device does not differentiate the apparatus claims from the prior art. MPEP 2114. A recitation with respect to the manner in which a claimed apparatus is intended to be employed, such as inserting sample tubes from the bottom, does not differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches all of the structural limitations of the claims. Therefore, since Leoncavallo or Schwartz teaches all the structural limitations of the claims including the compartment open at the top and bottom and Berthold provides the

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limitation of the compartments adapted to receive an entire sample tube, the claimed apparatus of claims 1 and 2 cannot be differentiated from Leoncavallo or Schwartz in view of Berthold based on inserting the sample tubes from the bottom.

Examiner notes that the tube(s) is/are not a positively recited element of the structure and defining the rack structure in terms of the tube(s) does not form a definite limitation to the structure. Referring to claim 1, the compartment does not have any required dimensions such as height. In claim 2, Applicant appears to be claiming that the dimensions are sufficient to enclose an entire tube within the compartment. From this it is clear that the compartment of claim 1 can enclose less than the entire tube, which is clearly met by both primary references.

Since Leoncavallo or Schwartz provides the limitations of claim 1 and Berthold provides the limitation of claim 2 with motivation, the combination suggests the invention of claim 2.

4. Referring to claims 3 and 5, Applicant maintains that Leoncavallo fails to anticipate or suggest a rack as claimed. Applicant further maintains that the passage of Verwohlt cited by the Examiner does not concern the shape of the storage compartments but the shape of the wells (16). Applicant further maintains that it would make no sense to use the device disclosed by Leoncavallo in such a way that the projection of each opening snaps in a groove of the outer surface of a sample tube because after that it would be difficult to remove the tube from the rack. Applicant further maintains that these documents provide no motivation and guidance for one of ordinary skill in the art to make the combination suggested by the Patent Office. Applicant further maintains that the combination of teachings of Leoncavallo and Verwohlt does not

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suggest the claimed invention. Applicant further maintains that the rejection of Schwartz in view of Verwohlt is unsound as set forth above with respect to claim 1. Applicant further maintains that one or ordinary skill in the art would not have been motivated to combined the disclosures of Schwartz and Verwohlt for the reasons set forth above with respect to Leoncavallo and Verwohlt.

As discussed above, Leoncavallo or Schwartz provides all the structural limitations in claims 1 and 4. Verwohlt provides the limitations of rectangular storage compartments of claim 3 and projection configured and dimensioned to snap in between two ridges of the outer wall of a sample tube of claim 5. Verwolht concerns the shape of the storage compartments, which are in the form of wells or openings. The wells are the storage compartments. It just different terminology for the same element. The wells or storage compartments both receive and hold a sample tube. Furthermore, the shape of the compartment does not affect the function of the apparatus, and mere shape of the is within the skill of the routineer in the art (In re Dailley, 149 USPQ 47). Applicant does not explain why it would not make sense to use the device disclosed by Leoncavallo or Schwartz in such a way that the projection of each opening snaps in a groove of the outer surface of a sample tube because it would be difficult to remove the tube from the rack. Referring to FIG. 7 in Leoncavallo or FIG. 4 in Schwartz, the projection could fit against the groove with movement of the projection limited by the ridges. Applicant does not explain why the tube would be difficult to remove from the rack. The tube is placed in the rack with the projection between the ridges and with slight movement the tube can be removed from the rack whether it be from the top or bottom.

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Since Leoncavallo or Schwartz provides the limitations of claims 1 and Verwohlt provides the limitation of claims 3 and 5 with motivation, the combination suggestions the invention of claims 3 and 5.

5. Applicant points out that neither Verwohlt nor Berthold teach or suggest a rack having storage compartments each of which is open at both ends (top and bottom) as required in the claims, much less a rack that allows a sample tube to be inserted into the storage compartment from either the top or bottom side of the frame. Applicant further maintains that there is no motivation in either of these documents to modify a rack so that a tube is removable from the storage compartment from either the top side of the frame or the bottom side of the frame with one and the same orientation of the sample tube with respect to the frame.

As discussed above, the primary references Leoncavallo or Schwartz provides the teaching or storage compartments each open at both ends such that a sample tube is insertable into the compartment from either the top or bottom side of the frame. The secondary references Verwohlt or Berthold need not have all the limitations in the claims. They only serve to provide the missing limitation and the motivation for providing the limitation to combine with the primary reference. Examiner emphasizes that method limitations or removing the tube from the compartment from either the top or bottom side of the frame with one and the same orientation of the sample tube is not given patentable weight in apparatus claims.

Conclusion

6. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing

date of this final action.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Elizabeth Quan whose telephone number is (703) 305-1947. The

examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Jill Warden can be reached on (703) 308-4037. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 879-9310 for regular

communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding

should be directed to the receptionist whose telephone number is (703) 308-0661.

Elizabeth Quan

Examiner

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eq

December 23, 2002

Wen Sodergust

PRIMARY EXAMINER